

AR201-13850

 Karen Hoffman

07/09/2002 10:09 AM

To: NCIC HPV@EPA, Jodi Burgess/DC/USEPA/US@EPA

cc:

Subject: HPVC Challenge Program, AR-201-Registration Number
PLEASE REMOVE REGISTRATION NUMBER FROM THIS
SUBMISSION.

----- Forwarded by Karen Hoffman/DC/USEPA/US on 07/09/02 10:08 AM -----

NATALIE_RUTHERFORD@fmc.com on 07/08/2002 04:25:40 PM



To: Rtk Chem/DC/USEPA/US@EPA, Richard Heftner/DC/USEPA/US@EPA, jessicas@peta.org

cc:

Subject: HPVC Challenge Program, AR-201-Registration Number

Please find attached FMC's response to the June 5 comments received from PCRM regarding our test plans for Methyl DVEster and MOP.

Please do not hesitate to contact me with any questions.

Sincerely,

Natalie Rutherford
Manager, Global Regulatory Affairs
FMC Corporation
1-215-299-6680



- HPVC-PCRM Response.doc

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July 8, 2002

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: PCRM Comments on FMC Corp. Test Plans for cyclopropanecarboxylic acid,3(2,2-dichloroethenyl)-2,2-dimethyl-,methyl ester and phenol,2-[(2-methyl-2-propenyl)oxy];methallyloxyphenol (MOP)

Dear Administrator Whitman:

FMC Corporation is in receipt and has taken note of the June 5 comments from the Physicians Committee for Responsible Medicine (PCRM) regarding the handling of test plans for the subject chemicals under the High Production Volume Chemical Challenge Program. As a member of the American Chemistry Council, we are firmly committed to our industry's Responsible Care[®] Program. We are equally committed to EPA's HPVC program, including those provisions on animal welfare.

We at FMC Corporation are sensitive to the protection of animals and have purposely taken a number of steps to reduce the need for animal testing. We have maximized the use of existing data, including literature on similar compounds. We support *in vitro* genotoxicity testing as proposed by the EPA. We have provided documentation to support closed system intermediate status for the subject compounds and have delayed proposed testing until 2003. We also intend to provide documentation that would qualify two additional compounds for reduced testing.

FMC Corporation has proposed a developmental toxicity test in our test plan, because it is required by the Guidance for Testing Closed System Intermediates for the HPV Challenge Program - "The reduced testing consists of the Screening Information Data Set (SIDS) minus the tests for repeated dose toxicity and reproductive toxicity, but including a developmental toxicity test."

Although not specified in our test plan, we plan to propose OECD Guideline 421 (Reproduction/Developmental Toxicity Screening Test) to satisfy this endpoint. We agree that OECD Guideline 414 (Prenatal Developmental Toxicity Study) would be inappropriate for a closed system intermediate, unless the results of the screening are

questionable. OECD Guideline 421 requires approximately 80 animals per test, whereas, OECD Guideline 414 requires approximately 1000 animals per test. For the 2 compounds under consideration, more than 1800 animals will be saved.

On another point, we believe that we have provided the appropriate amount of detail on the process of each subject compound to support the claim that the process is closed, while not revealing confidential business information.

In closing, we at FMC Corporation actively support the HPVC Program, its primary goal to ensure that important hazard information is made available to the public and its provisions to reduce animal testing.

Sincerely,

Natalie Rutherford
Manager, Global Regulatory Affairs
FMC Corporation

cc:

Rich Hefter, Chief of the High Production Volume Challenge Program
Jessica Sandler, People for the Ethical Treatment of Animals